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Applicant : Warren M. Zapol et al.
Serial No.: 08/353,508
Filed : December 9, 1994
Title : METHODS FOR TREATING PULMONARY VASOCONTRICION AND
ASTHMA

Art Unit:
Examiner:

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INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO 1449. This statement is being filed within three months of the filing date of the application.

Under 35 USC 120, this application relies on the earlier filing date of application serial number 07/767,234, filed on September 27, 1991. The following references were submitted to and/or cited by the Office in the prior application and, therefore, are not provided in this application:

U.S. Patent No. 4,287,040 (Alamaro).

U.S. Patent No. 4,336,798 (Beran).

U.S. Patent No. 4,877,589 (O'Hare).

U.S. Patent No. 4,010,897 (Treharne et al.).

U.S. Patent No. 4,915,915 (Treharne et al.).

U.S. Patent No. 4,297,123 (Wyse et al.).

U.S. Patent No. 3,785,377 (Jorgensen).

U.S. Patent No. 4,667,668 (Wetterlin).

U.S. Patent No. 4,592,348 (Waters et al.).

Date of Deposit March 9, 1995

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Mary Jane DiPalma
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U.S. Patent No. 4,534,343 (Nowacki et al.).

U.S. Patent No. 4,852,561 (Sperry).

U.S. Patent No. 4,954,526 (Keefer).

U.S. Patent No. 5,155,137 (Keefer et al.).

U.S. Patent No. 5,208,233 (Keefer et al.).

PCT Patent No. WO 92/17445 (15/10/92).

PCT Patent No. WO 93/12068 (24/06/93).

Great Britain Patent No. GB-A-2 144 997 (20/03/85).

Great Britain Patent No. 2178958 (2/87)

Blomqvist et al., Inhaled Nitric Oxide (NO): A

Selective Pulmonary Vasodilator Reversing Human Hypoxic Pulmonary Vasoconstriction (HPV), Circulation 84:361, 1991.

Desai et al., Involvement of Nitric Oxide in the Reflex Relaxation of the Stomach to Accommodate food or Fluid, Nature 351:477, 1991.

Donahoe et al., Production of O₃, NO, and N₂O in a Pulsed Discharge at 1 Atm, Ind. Eng. Chem. 16:208-215, 1977.

Fractacci et al., Inhaled Nitric Oxide, Anesthesiology 75:990-999, 1991.

Pepke-Zaba et al., Inhaled Nitric Oxide as a Cause of Selective Pulmonary Vasodilation in Pulmonary Hypertension, The Lancet 338:1173-1174, 1991.

Rimar et al., Prolonged Duration of Inhaled Nitric Oxide Induced Vasodilation in Perfused Rabbit Lungs, Circulation 84:362, 1991.

Roberts, Jr. et al., Inhaled Nitric Oxide (NO): A Selective Pulmonary Vasodilator for the Treatment of Persistent

Pulmonary Hypertension of the Newborn (PPHN), Circulation 84:1279, 1991.

Dupuy et al., Bronchodilator Action of Inhaled Nitric Oxide in Guinea Pigs, J. clin. Invest. 90:421-428, 1992.

Kacmarek et al., Nitric Oxide as a Bronchodilator in Methacholine Induced Bronchospasm in Mild Asthmatics, 1993 ALA/ATS International Conference, May 16-19, 1993, San Francisco, CA #21556 (Abstract).

Messent et al., The Pulmonary Physician and Critical Care, Thorax 47:651-656, 1992.

Swami et al., the Pulmonary Physician and Critical Care, Thorax 47:555-562, 1992.

Frostell, MD, PhD et al., Inhaled Nitric Oxide: A Selective Pulmonary Vasodilator Reversing Hypoxic Pulmonary Vasoconstriction, Circulation 83:2038-2047, 1991.

Dalby et al., Comparison of Output Particle Size Distributions from Pressurized Aerosols Formulated as Solutions or Suspensions, Pharmac. Re. 5:36-39, 1988.

Buga et al., Endothelium-Derived Nitric Oxide Relaxes Nonvascular Smooth Muscle, European J. of Pharmc. 161:61-72, 1989.

Ishii et al., A Simple and Sensitive Bioassay Method for Detection of EDRF with RFL-6 Rat Lung Fibroblasts, Am. J. Physiol. 261:H598-H603, 1991.

Stuart-Smith et al., Epithelium, contractile Tone, and Responses to Relaxing Agonists in Canine Bronchi, J. Appl. Physiol. 69:678-685, 1990.

Suzuki et al., The Relationship Between Tissue Levels of Cyclic GMP and Tracheal Smooth Muscle Relaxation in the Guinea-Pig, Clinical & Pharmacol. & Physiol. 13:39-46, 1986.

Tan et al., Cigarette Smoke Activates Guanylate Cyclase and Increases Guanosine 3', 5' -Monophosphate in Tissues, Science 198:934-936, 1977.

Maron et al., Cigarette Smoke Causes Acute Fluctuations in the Cyclic GMP Content of the Isolated Intact Lung, Respiration 43:39-44, 1984.

Heaslip et al., Co-Regulation of Tracheal Tone By Cyclic AMP- and Cyclic GMP-Dependent Mechanisms, J. Pharmacol. & Experms. 243:1018-1026, 1987.

Moncada et al., Nitric Oxide: Physiology, Pathophysiology, and Pharmacology, Pharmacol. Reviews 91:109-141, 1991.

Kalant et al., Drugs and the Respiratory System, Chapter 39 362-397, 1989.

Gilman et al., Vascular Effects of Cigarette Smoke in Isolated Pig Lungs, Am. Rev. Respir. Dis. 124:549-553, 1981.

Flenley, Today's Treatment of Airway Obstruction.. and Tomorrow's?, Respiration 55:4-9, 1989.

Physician's Desk Reference, pages 969-971, 2322-2323, 668-670.

Edwards et al., Activation of Hepatic Guanylate Cyclase by Nitrosyl-Heme Complexes, Biomed. Pharmacol. 30:2531-2538, 1981.

Garg et al., Nitric Oxide Generating Vasodilators Inhibit Mitogenesis and Proliferation of BALB/C 3T3 Fibroblasts

by a Cyclic GMP-Independent Mechanism, Biochem. Biophysl. Re. Comm. 171:474-479, 1990.

Schmidt et al., Stimulation of Soluble Coronary Arterial Guanylate Cyclase by Sin-1, European J. Pharmaclgy. 122:75-79, 1986.

McNamara et al., Adenosine 3', 5' Monophosphate Formation by Preparations of Rat Liver Soluble Guanylate Cyclase.....and Other Nitroso Compounds, Can. J. Physiol. Pharmacol. 58:1446-1456, 1980.

Ignarro, Biosynthesis and Metabolism of Endothelium-Derived Nitric Oxide, Annu. Rev. Pharmacol. Toxicol. 30:535-560, 1990.

Allen and Hanbury, Product Information Bulletin on Ventolin, 1990.

Boje et al., Endothelial Nitric Oxide Generating Enzyme(s) in the Bovine Aorta: Subcellular Location and Metabolic Characterization, Am. Soc. Pharmaclgy. & Experm. Therapeutics 253:20-26, 1990.

Southern et al., Inhibition of Insulin Secretion by Interleukin-1 β and Tumor Necrosis Factor- α via an L-Arginine-Dependent Nitric Oxide Generating Mechanism, FEBS 276:42-44, 1990.

Garg et al., Nitric Oxide-Generating Vasodilators and 8-Bromo-Cyclic Guanosine Monophosphate Inhibit.....Vascular Smooth Muscle Cells, J. Clin. Invest. 83:1774-1777, 1989.

Garg et al., Nitric Oxide-Generating Vasodilators Inhibit Mitogenesis and Proliferation of BALB/C 3T3 by a Cyclic

GMP-Independent Mechanism, Biochem. Biophys. Res. Comm. 171:474-479, 1990.

Brune et al., Activation of a Cytosolic ADP-Ribosyltransferase by Nitric Oxide-Generating Agents, J. Biol. Chem. 264:8455-8458, 1989.

Curran et al., Nitric Oxide and Nitric Oxide-Generating Compounds Inhibit Hepatocyte Protein Synthesis, FASEB J. 5:2085-2092, 1991.

Ignarro, Endothelium-Derived Nitric Oxide: Actions and Properties, FASEB J. 3:31-36, 1989.

Peckham, Physiologic Factors Affecting Pulmonary Artery Pressure in Infants with Persistent Pulmonary Hypertension, J. Ped. 6:1005-1010, 1978.

Zapol et al., Pulmonary Circulation During Adult Respiratory Distress Syndrome, Marcel Dekker, 241-273, 1985.

Fox et al., Pulmonary Hypertension in the Perinatal Aspiration Syndromes, Pediatrics 59:205-211, 1977.

Dworetz et al., Survival of Infants with Persistent Pulmonary Hypertension without Extracorporeal Membrane Oxygenation, Pediatrics 84:1-6, 1989.

Fishman, Pulmonary Hypertension and Cor Pulmonale, Chapter 64 pp. 999-1048.

Radermacher et al., Comparison of Ketanserin and Sodium Nitroprusside in Patients with Severe ARDS, Anesthesiology 68:152-157, 1988.

Vlahakes et al., The Pathophysiology of Failure in Acute Right Ventricular Hypertension: Hemodynamic and Biochemical Correlations, Circulation 63:87-95, 1981.

Ignarro et al., Endothelium-Derived Relaxing Factor Produced and Released from Artery and Vein is Nitric Oxide, Proc. Natl. Acad. Sci. USA 84:9265-9269, 1987.

Palmer et al., Nitric Oxide Release Accounts for the Biological Activity of Endothelium-Derived Relaxing Factor, Nature 327:524-526, 1987.

Ignarro, Biological Actions and Properties of Endothelium-Derived Nitric Oxide Formed and Released From Artery and Vein, Dept. Pharmacology. pp. 23-278.

Higgenbottom et al., Am. Rev. Resp. Dis. Suppl. 137:107, 1988.

Zapol et al., Pulmonary Hypertension in Severe Acute Respiratory Failure, N.E. J. Med. 296:476-480, 1977.

Meyer et al., Nitric Oxide (NO), a New Test Gas for Study of Alveolar-Capillary Diffusion, Eur. Respir. J. 2:494-496, 1989.

Hounam et al., particle Deposition pp. 125-156.

Ignarro, Endothelium-Derived Nitric Oxide: Actions and Properties, FASEB J. 3:31-36, 1989.

Archer et al., Comparison of the Hemodynamic Effects of Nitric Oxide and Endothelium-Dependent Vasodilators in Intact Lungs, J. Appl. Physiol. 68:735-747, 1990.

Furchgott et al., Endothelium-Derived Relaxing and Contracting Factors, FASEB J. 3:2007-2018, 1989.

Archer et al., Hypoxic Pulmonary Vasoconstriction is Enhanced by Inhibition of the Synthesis of an Endothelium Derived Relaxing Factor, Biochem. Biophysl. Re. Comm. 164:1198-1205, 1989.

Brashers et al., Augmentation of Hypoxic Pulmonary Vasoconstriction in the Isolated Perfused Rat Lung by in Vitro Antagonists of Endothelium-Dependent Relaxation, J. Clin. Invest. 82:1495-1502, 1988.

Ignarro et al., Mechanism of Vascular Smooth Muscle Relaxation by Organic Nitrates, Nitrites, Nitroprusside and Nitric Oxide:....S-Nitrosothiols as Active Intermediates, J. Pharmacol. Experm. Ther. 218:739-749, 1981.

Kadowitz et al., Pulmonary Vasodilator Responses to Nitroprusside and Nitroglycerin in the Dog, Clin. Invest. 67:893-902, 1981.

Naeije et al., Effects of vasodilators on Hypoxic Pulmonary Vasoconstriction in Normal Man, Chest 82:404-410, 1982.

Flavahan et al., Respiratory Epithelium Inhibits Bronchial Smooth Muscle Tone, J. Appl. Physiol. 58:834-838, 1985.

Hugod, Effect of Exposure to 43 ppm Nitric Oxide and 3.6 ppm Nitrogen Dioxide on Rabbit Lung, Int. Arch. Occup. Environ, Health 42:159-167, 1979.

Nakajima et al., Biological Effects of Nitrogen Dioxide and Nitric Oxide, Nitrogen Oxides 121-141.

Packer, Is It Ethical to Administer Vasodilator Drugs to Patients with Primary Pulmonary Hypertension, Chest 95:1173-1175, 1989.

Agabwal et al., Nature pp. 915-916, 1965.

Stavert et al., Nitric Oxide and Nitrogen Dioxide..... Concentrations for Brief Periods, Inhalation Toxicology 2:53-67, 1990.

Morel et al., Acute Pulmonary Vasoconstriction and Thromboxane Release During Protamine Reversal of Heparin Anticoagulation in Awake Sheep, Circulation Research 62:905-915, 1988.

Morel et al., C5 α and Thromboxane Generation Associated with Pulmonary Vaso-and Broncho Constriction during Protamine Reversal of Heparin, Anesthesiology 66:597-604, 1987.

Borland et al., A Simultaneous single Breath Measurement of Pulmonary Diffusing Capacity with Nitric Oxide and Carbon Monoxide, Eur. Respir. J. 2:56-63, 1989.

Altabef et al., Intravenous Nitroglycerin for Uterine Relaxation of an Inverted Uterus, Am. J. Obstet. Gynecol. 166:1237-1238, 1992.

Oxytocin. Prostaglandins. Ergot Alkaloids. Tocolytic Agents., Chapter 39, pp. 942-945.

Resnick et al., Evaluation and Medical Management of Urinary Incontinence, Anesthesia pp. 3-6, 1992.

Zapol et al., Regional Blood Flow During Simulated Diving in the Conscious Weddell Seal, J. Appl. Physiol. 47:968-973, 1979.

Contractor et al., Development and Evaluation of an Inhalation Aerosol of Nitroglycerin, J. Pharm. Sci. 63:907-911, 1974.

Jansen et al., The Relaxant Properties in Guinea Pig Airways of S-Nitrosothiols, J. Pharmacology and Experimental Therapeutics 261:154-160, 1992.

Cremona et al., Endothelium-Derived Relaxing Factor and the Pulmonary Circulation, Lung 169:185-202, 1991.

Dinh Xuan et al., Acetylcholine and Adenosine Diphosphate Cause Endothelium-dependent Relaxation of Isolated Human Pulmonary Arteries, Eur. Respir. J. 3:633-638, 1990.

Dinh Xuan et al., Primary Pulmonary Hypertension: Diagnosis, Medical and Surgical Treatment, Respiratory Medicine 84:189-197, 1990.

Dinh Xuan et al., Non-prostanoid Endothelium-derived Vasoactive Factors, J. International Medical Research 17:305-315, 1989.

Foubert et al., Safety Guidelines for Use of Nitric Oxide, The Lancet 339:1615-1616, 1992.

Kreye et al., Comparison of Sodium Nitroprusside and Isoprenaline Aerosols in Histamine-Induced Bronchial Asthma of the Guinea Pig, Naunyn-Schmiedeberg S Arch Pharmacol. 306:203-207, 1979.

Supplementary European Search Report for corresponding EP application NO. 92902708.4, mailed 19 October 1993.

PCT Search Report from the corresponding PCT Patent Application No. PCT/US93/06091.

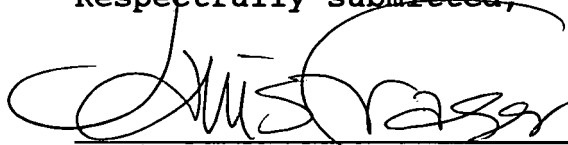
Copies of the remaining two publications listed on the form 1449, WO93/12068 and WO92/17445, are enclosed.

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Respectfully submitted,

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